ZONARE 510(k) Summary of Safety & Effectiveness

Prepared in accordance with 21 CFR Part 807.92(c)

APR 1 3 2012

The assigned 510(k) number is: $\frac{K120703}{}$

Applicant Information:

Date Prepared:

February 22, 2012

Name:

ZONARE Medical Systems, Inc.

420 North Bernardo Avenue Mountain View, CA 94043

Contact Persons:

Linda J. Moore

Director, Regulatory Affairs & Quality Assurance

Telephone Numbers: 650-230-2724

Fax Number:

650-967-9036

Email

lmoore@zonare.com

Device Information:

Trade Name:

ZONARE ZS3 Ultrasound System

Device Name:

ZONARE Diagnostic Ultrasound System

	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

Marketed Device(s): The ZONARE ZS3 Ultrasound System is a combination of the currently marketed

ZONARE z.one Ultra Ultrasound System consisting of a convertible scanner and cart(s) previously cleared on (K082326) (K101091). The ZS3 combines the scanner and cart into a singular unit, which still resembles the currently marketed z.one Ultra Ultrasound system in looks, features and functionalities, including the same software revision,

driving both systems.

Device Description: The ZONARE ZS3 is a general purpose diagnostic ultrasound system which consists of a the previous cleared portable scanner integrated into the ZONARE z.one Ultra Smartcart to enable the user to focus on performing patient scans with a more streamline unit. No longer convertible, the ZONARE ZS3 will still be considered a mobile system as it will be lightweight and easy to move from room to room. The new system, which uses the same software base as the currently approved z.one Ultra ultrasound system, will have hardware changes which are minimal, but require some redesign in the cart base in order to put working components of the scanner inside the cart. Otherwise, the user interface and other features/functionalities of the system are substantially equivalent to the ZONARE Ultra Ultrasound System in both indications for use and system functionality. The new ZS3 will be based on the ZONARE's patented zone sonography, and with the scanner's internal components now inside the cart base, the ZS3, without compromising safety and

effectiveness, should improve image quality through a higher signal to noise ratio, as well as support a wider range of future enhancements. Features, such as multi transducer ports will be standard in the system as will an embedded hard drive and DVD. The system will function with the ZONARE Ultra current suite of transducers. Signals received from the transducer module are digitized and preprocessed. The transducer module comes into contact with the patient and both transmit and receive ultrasound energy. There is no difference between the currently cleared ZONARE transducers (K101091) and the transducers as shown in this submission for the ZS3.

The system provides holders for transducer models, and will be offered with battery chargers and other accessories. The modification for this submission includes no new indication for use but does have 1 transducer the C10-3 added as appendix E to the ZONARE z.one Ultra Ultrasound system which will be declared new to this system.

Indications For Use: The device is intended for use by a qualified physician for ultrasound evaluation of: Ophthalmic; Fetal/obstetric, gynecological; Abdominal (renal, GYN/Pelvic; Intra-operative (abdominal, thoracic, and vascular), Intra-operative neurological; Pediatric; Small organ (thyroid, breast, testes, etc), Adult & Neonatal Cephalic; Trans-rectal, Trans-vaginal, Trans-cranial, Trans-esophageal (non-cardiac and cardiac); Musculoskeletal (conventional & superficial); 3D/4D; Cardiac – Adult/Pediatric/Fetal; Echo, Intra-Cardiac; Pelvic; Peripheral vascular; harmonic tissue and contrast imaging and Tissue elasticity, Vet and others as stated in 1.3.

<u>Comparison with Predicate Device:</u> With respect to features and applications, the ZONARE ZS3 Ultrasound System, is comparable and substantially equivalent to the currently marketed ZONARE z.one Ultra Ultrasound System, and the additional predicate device listed in predicate devices section in terms of features and functionality. Additionally, the ZONARE ZS3 Ultrasound System and the ZONARE z.one Ultra Ultrasound System have the same important safety and effectiveness features, as well as share the same software, materials, and design/construction as shown in the predicate device comparison table.

<u>Non-clinical tests:</u> The device has been evaluated according to the applicable medical device quality systems, safety standards for acoustic output, biocompatibility, verification and validation, cleaning, and disinfection effectiveness as well as for thermal, electrical, and mechanical safety, those applicable to ZONARE's ultrasound product(s) are:

ISO 14971	Medical Devices – applications of risk management to medical devices
IEC/UL 60601-1	Medical Electrical Equipment (MEE) - General Requirements for Safety
IEC 60601-1-1	Medical Electrical Equipment for Systems
IEC 60601-1-2	EMC
IEC 60601-1-4	MEE – Programmable electrical medical systems
IEC 60601-2-37	Safety of ultrasonic medical diagnostic and monitoring equipment
IEC 62304	Medical Device software – software life cycle processes
ISO 10993	Biological evaluation of medical devices
AlUM	Medical Ultrasound Safety, American Institute of Ultrasound in Medicine

Clinical Tests: Non Required

<u>Conclusion</u>: The device conforms to applicable medical device safety standards and compliance for safety and effectiveness which is verified through defined verification and validation, and market surveillance. Driven by the same software, which is used by the currently marketed ZONARE z.one Ultra Ultrasound System, which has been shown to be safety and effective, the ZONARE ZS3 Ultrasound system is substantially equivalent with respect to safety and effectiveness to devices current cleared for market.



Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

ZONARE Medical Systems, Inc. % Mr. Mark Job Responsible Third Party Official Regulatory Technology Services 1394 25th Street NW BUFFALO MN 55313

APR 1 3 2012

Re: K120703

Trade/Device Name: The ZONARE ZS3 Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, ITX, and IYO

Dated: March 28, 2012 Received: March 29, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the The ZONARE ZS3 Ultrasound System, as described in your premarket notification:

Transducer Model Number

Curvilinear Transducer C4-1
Curvilinear Transducer C6-2
Curvilinear Transducer C9-3
Phased (Sector) Array Transducer C10-3
Curvilinear Transducer C8-3 (3D/4D)
Curvilinear Transducer C9-4t
Phase (Sector) Array Transducer P4-1c
Phased (Sector) Array Transducer P10-4
Endo-Cavity Transducer E9-4
Endo-Cavity Transducer E9-3 (3D)

Linear Transducer L10-5
Linear Transducer L8-3
Linear Transducer L12-4v
Linear Transducer L14-5sp
Linear Transducer L14-5w

Tran-Esophageal Transducer P8-3TEE

St. Jude EP ViewFlex PLUS ICE Catheter model # VF-PM Part #09-2005 (off the shelf)(P9-3ic)

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Jeffrey Ballyns at (301) 796-6105.

Sincerely Yours

Janine M. Morris
Acting Director

Division of Radiological Devices

Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and Radiological Health

Enclosure(s)

Indications for Use Statement

510(K) Number (if known):	
Device Name:	The ZONARE ZS3 Ultrasound syst	em
Indications for use	»:	
gynecological; Ab operative neurolog rectal, Trans-vagir & superficial); 3D	dominal (renal, GYN/Pelvic; Intra-operatical; Pediatric; Small organ (thyroid, breatial, Trans-esophageal (non-	Itrasound evaluation of Ophthalmic; Fetal/obstetritive (abdominal, thoracic, and vascular), Intrast, testes, etc), Adult & Neonatal Cephalic; Transcardiac and cardiac); Musculoskeletal (convention), Intra-Cardiac; Pelvic; Peripheral vascular;
	•	
		•
_	n Use AND/OR FR 801 Subpart D)	Over-The-Counter Use(21 CFR 801 Subpart C
. (PLEASE DO NOT WRITE BELOW THIS LINE-CON	TINUE ON ANOTHER PAGE IF NEEDED)
	Concurrence of CDRH, Office of In Vit	tro Diagnostic Devices (OIVD)
Division/Sign-Off Office of In Vitro D	jagnostic Devices	
Evaluation and Safe	ty 703	Page 1 of

1.3.	Diagnostic Ul	ıraso	una 1.	naicau	ions to	r use				,
510(K) Num	ber (if known):		•							
, <i>,</i>	: ZONARE ZS3 U	Iltrase	ound D	liagnost	ic Syste	m		_		•
	System Union of					***				
	r Use: This device is inte					tmaasuud assalssa	tion of the follow	uina Estal d	Shdominal Int	t-monamtiva
Pediatric, Ophthalm	ic, Intra-cardiac, Small orga onatal/Adult cephalic. Vascu	n/parts (t	oreast/teste	s, thyroid, e	tc), Transva	ginal, Transrect	al, Transcranial,	Trans - esoph	n, Trans-urethi	ral, OB/GYN,
00.2.14 12.2.4	with a board in the property	Tiri	50 1 41	Contact Contacts	ile and the state of the state	المراجع	Addressed the Nove with 1 MB	CRECCIAL DES	ī .	
	(2) 大学などの表現できます。	Mode	of Operatio	n 题 安约5 	CWD	1	建 新发发了4年	-ATTAGAÇORISM		
General	Specific	В	М	PWD ²	CWD Aux	Color Doppler ¹	Combined Modes ⁴	Other ^{5, 8}		
Ophthalmic	Ophthalmic Fetal	N	N ·	N N		N	N	N ³		
	Abdominal	N	N	N		N	N	N ⁵		
	Intra-operative (Specify) ⁶	N	N	N		N	N	N ²	ļ.	
	Intra-operative (Neuro)	N		N		N	N	N ⁵	l.	
	Laparoscopic	<u> </u>		<u> </u>						•
	Pediatric	N	N	N		.N	N	N ₂		
•	Pediatric Aux . Small Organ (Thyroid,			- 	 	-	 	N ³		
	Breast, Testes, etc.)	N	N	N		N .	N	N ⁸		
	Neonatal Cephalic	N	N ·	N		N	N	N ²		
General	Adult Cephalic	N	N	N		N	N	N ³		
Application	Trans-rectal	N	N	N		N	N	N ²		
	Trans-vaginal	N	N	N		N	N	N ₂		
	Trans-urethral Trans-esoph. (non-Card.)	N	N	N		N	N	N ⁵	ı	
	Musculo-skel.	 						N ^{5, 8}	ı	
	(Conventional)	N	N	N		N .	N	N.,		•
•	·Musculo-skel.	N	N	IN	,	N	N	N5, 8		
,	(Superficial)	 		 	<u> </u>			 	-	
	Intra-luminal Other (Specify)	 			<u> </u>			 	ı	
	(3D/4D)	N	N	N :	•	N	N .			
,	Cardiac Adult	N¹	N	N		N.	N	N ²		
	Cardia Adult Aux						<u> </u>			
	Cardiac Pediatric	N	N	N		N	N	N ⁵	Į.	
Cardiac	Cardiac Pediatric Aux Trans-esoph. (Cardiac)	N	N	N	 	N	N	N ⁵	i .	
	Other (Specify)			 		1		† 		
	(3D/4D)	N	N	N		Ņ	N			•
	Other (Intra-Cardiac)*	N·	N	N		N.	ļ <u></u>	1.5		
	Peripheral Vessel	N	N	N		N -	N	N ₈		
Peripheral vascular	Peripheral Vessel Aux		<u> </u>	 			 		<i>'</i>	
	Other (Specify) (3D/4D)	N	N	N	<u></u>	N	N			
 Includes B-Mode and Includes PWD-Mode Includes Color Dopple Includes B+M. B+M+ Color M-Mode (CM) Abdominal includes re 	abdominal, thoracic (cardiac) a	II) ion Rate P oler (DPD 3+CD+PW	WD-Mode (), and Power D where CI	(HPRF) r Doppler (PD))					
	Prescription Use(Part 21 CFR 801 Subp		٠.	AND/OR	. (2	ver-The-Cour 21 CFR 801 St	ubpart C		,	
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Clinical Application General (Track Only)	Jse: Diagnostic ultra	asound		g or fluid i	flow analy	ysis of the hu	man body as	follows:		
General		· Mode (
General		I WILKLE (of Omamoic				10 m 1 m			
		T .			CWD	Color	Combined			
	(Track I & III)	· B	M	PWD ²	aux	Doppler ³	Modes ⁴	Other ^{5, 8}	•	
	phthalmic					1 ''		1 1		
	etai	P.	I P	P		P	P	†		
	abdominal .	P	P	Р	·	Р	P			
	ntra-operative (Specify)			†·					•	
	ntra-operative (Neuro)		1							
	aparoscopic				1					
	ediatric	P	P	P		P	P			
<u> </u>	ediatric Aux .		T	1					•	
	mall Organ (Thyroid,	 	1	1					•	
B	reast, Testes, etc.)	1	1		<u> </u>			<u> </u>		
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	ardiac Adult Aux			<u> </u>						
C	ardiac Pediatric		<u> </u>		•					
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	ther (intra-cardiac)*	·								
. P	eripheral Vessel									
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Peripheral vascular P	eripheral Vessel Aux					Added under A				

elasticity			
Prescription Use(Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use(21 CFR 801 Subpart C	*
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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Devices

Evaluation and Safety
510(K) K120703

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	e: Curvilinear Tran						•				
ndications	for Use: Diagnostic ultra	asound	imaging	g or fluid f	low analy	sis of the hu	ıman body as	follows:			
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General	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ^{5, 8}			
phthalmic	Ophthalmic		 			1					
-	Fetal	Р	P	P	1	P	P .	P ⁵			
•	Abdominal ⁶	Р	P	P		P	P	P ⁵			
	Intra-operative (Specify)							:			
	Intra-operative (Neuro)			·							
	Laparoscopic						<u> </u>				
•	Pediatric	P	P	P ·		P	P	P ⁵			
	Small Organ (Thyroid, Breast, Testes, etc.)										
	Neonatal Cephalic										
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	Trans-vaginal										
	Trans-urethral		<u> </u>			ļ	ļ	<u> </u>			
	Trans-esoph. (non- Card.)		<u> </u>								
	Musculo-skel. (Conventional)										
	Musculo-skel. (Superficial)										
	Intra-luminal			<u> </u>		<u> </u>	·	i.——			
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· · · · -	Other (Specify) Peripheral Vascular	P	P	P		P	P	P ⁵			
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Prescription Use	AND/OR	Over-The-Counter Use
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itro Diagnostic Devices

⁵ Color M-Mode (CM)
6 Abdominal includes renal, GYN/Pelvic
7 Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

^{8.} Freehand tissue elasticity

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	e: Curvilinear Tran									
	for Use: Diagnostic ultra				flow analy	sis of the hu	man hody as	follows:		
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General	Specific (Track I & III)	В	М	PWD ²	CMD	Color Doppler ³	Combined Modes [‡]	Other ^{5, 8}		
Ophthalmic	Ophthalinic	<u> </u>	<u> </u>			ļ. <u></u>	_	<u> </u>		
	Fetal	P	P	P		P	P	P ⁵		
	Abdominal ⁶	P	Р.	P	<u> </u>	P	P	P ⁵		
	Intra-operative (Abdominal)	P	P	P		Р .	Р	P ⁵		
	Intra-operative (Vascular)	P	. P	Р		P	P	P ⁵		
	Laparoscopic]							
	Pediatric	P	P	P		Р	P	P ⁵		
	Small Organ (Thyroid, Breast, Testes, etc.)									
	Neonatal Cephalic								•	
eneral oplications	Adult Cephalic			<u> </u>		<u> </u>		<u> </u>		
prications	Trans-rectal				<u> </u>					
	Trans-vaginal									
	Trans-urethral .									
	Trans-esoph (non- Card.)			_						
	Musculo-skel (Conventional)	P	P	P		P	P	p ⁵		
	Musculo-skel. (Superficial)	Р	Р	P		Р	Р	P ⁵		
	Intra-luminal			·		<u> </u>				
	Other (Specify) (3D/4D)							<u> </u>		
	Cardiac Adult				<u> </u>			ļ !		
ardiac	Cardiac Pediatric							<u> </u>		
aruidt .	Trans-esoph. (Cardiac)				<u> </u>			 		
	Other (Specify)	l				<u> </u>		 		
eripherál	Peripheral Vascular	Р	P	P	ļ	P	Р	P ⁵		
ascular	Other (Specify) tion; P=previously cleared b		1			<u> </u>				

Prescription Use	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C
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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

itro/Diagnostic Devices

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

						•		
• ,	nber (if known): e: ZONARE ZS3 U	Itrasc	ound D	Diagnost	ic Syste	m		
Device Name	: Phased (Sector) A	Array asound	Trans imaging	ducer C	C10-3 flow analy	rsis of the hu	man body as fo	
General	Specific (Track I & III)	В	M M	PWD ²	CWD	Color Doppler	Combined Modes ⁴	Oth
Ophthalmic	Ophthalmic							
	Fetal	N	N	N		N	N	N ⁵ .
	Abdominal ⁶	N	N	N		N	N	N ⁵
	Intra-operative (specify)	N	N	N		N	N	N ³
,	Intra-operative (Neuro)	N	N	N		N _	N	N ₃
	Laparoscopic							
1	D. dissuis	NI	N.	N.		N.	N	NI-3

General	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³	Modes ⁴	Other 8
Ophthalmic	Ophthalmic							
	Fetal	N	N	N		N	N	N ⁵ . •
	Abdominal ⁶	N	N	N		N	N	N ⁵ .
•	Intra-operative (specify)	N	N	N		N	N	N ⁵
•	Intra-operative (Neuro)	N	N	N		N _	N	N ^s
	Laparoscopic							
	Pediatric	N	N	N		N	N	N ³
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	N	N	N		N	N	N ⁵
General	Adult Cephalic/ trans	N	N	N		N	N	N ⁵
application	Trans-rectal		 					—
	Trans-vaginal	1		1	-	<u> </u>		
	Trans-urethral	<u> </u>						1
	Trans-esoph (non- Card.)							
	Musculo-skel. (Conventional)							
•	Musculo-skel. (Superficial)							
	Intra-luminal	i	1.					
	Other (Specify)							
	Cardiac Adult	N	N .	N		N	N	N ³
•	Cardiac Pediatric	N	N	N		N	N	N ³
Cardiac	Trans-esoph. (Cardiac)							· ·
	Other (Specify) (3D/4D)							
	Peripheral Vascular	N	Ň	N		N	N	N ⁵
Peripheral vascular	Other (Specify) 3D/4D							

Includes B-Mode and Harmonic (contrast) imaging (HI)	•	•	
Includes PWD-Mode imaging and High Pulse Repetition Rate	te PWD-Mode (HPRF)		
Includes Color Doppler (CD), Directional Power Doppler (D			
Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+	PWD where CD could	represent (CD, DPD, PD, or BD)	
Color M-Mode (CM)			
Abdominal includes renal, GYN/Pelvic			•
Intra operative include abdominal, thoracic (cardiac) and vas	cular (PV)	• •	
Freehand tissue elasticity		_	
Prescription Use	AND/OR	Over-The-Counter Use	
• — —	. AND/OR		
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C	

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Devices

Evaluation and Safety 510(K) K176703

510(K) Number (if known):_____

Device Name: Curvilinear Transducer C8-3 (3D/4D)

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode	f Operati	on 📆 📆			engerica especialists	
General	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ^{5, 8}
Ophthalmic	Ophthalmic						 	<u> </u>
	Fetal	P	P	P		P	P	P ³
•	Abdominal ⁶	P	P	P		P	Р	P ³
•	Intra-operative (Specify)			. !				
į	Intra-operative (Neuro)		 				i	
	Laparoscopic							
	Pediatric	P	P	P		P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)				,			
	Peonatal Cephalic		1			j -		
General	Adult Cephalic		1					
applications	Trans-rectal		<u> </u>					
••	Trans-vaginal							<u> </u>
	Trans-urethral							
	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)		-	_				
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify) (3D/4D)	P	P	P		Ь.	P	P ³
	Cardiac Adult			ļ			 	
Cardiac	Cardiac Pediatric		<u> </u>				<u> </u>	
Carulac	Trans-esoph. (Cardiac)		 	<u> </u>		ļ		
	Other (Specify)		<u> </u>	<u> </u>	. –	<u> </u>	 	P ⁵
Peripheral	Peripheral Vascular	P	P	P		P	P	P
Vascular	Other (Specify)				<u> </u>			<u> </u>

N = new indication; P=previously cleared by FDA 510(k) K101091, E=Added under Appendix E

Prescription Use	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C
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Evaluation and Safety

510(K) Number	(if known):	
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¹ Includes B-Mode and Harmonic (contrast) imaging (HI)

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

³ Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

⁴ Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[§] Freehand tissue elasticity

Device Name: Curvilinear Transducer C9-4t

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode	of Operati	ón 🔭 🗀		5 - 71, 11		<u> </u>
General (Track I Only)	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ^{5, 8}
Ophthalmic	Ophthalmic	+	+	 -		Dopplet	ivioues	ļ
Оришание	Fetal	 	 	 				٠.
	Abdominal	P	P	P	_	P	P	-
		r	+	<u> </u>	 -	r	F	
	Intra-operative (Specify) ⁷							<u> </u>
	Intra-operative (Neuro)	<u>.</u>	<u> </u>					
,	Laparoscopic			<u> </u>			<u> </u>	
	Pediatric	Р	P	P		P	P	
	Small Organ (Thyroid,							
	Breast, Testes, etc.)			1				
	Neonatal Cephalic	P	P	P		P	P	
	Adult Cephalic		ļ				,	
General	Trans-rectal]				I	·	
application	Trans-vaginal							
application	Trans-urethral		,					
	Trans-esoph. (non-					1		
	Card.)							
	Musculo-skel.	Р	Р	Р		Р	Р	
	(Conventional)	,	F	1		<u>'</u>	<u> </u>	
	Musculo-skel.	Р	Р	P		Р	P	
	(Superficial)	Г	1	<u>'</u>		1 .	1	
	Intra-luminal							
	Other (Specify)							
	(3D/4D)	P	P	P		Р	Р .	
	Vet abdominal	'	'	1		1 '	1 -	
		_		 	•	<u> </u>		
	Cardiac Adult	<u> </u>	P	l n	•	P	P	
	Cardiac Pediatric	P	P	P		P	· P	
Cardiac ,	Trans-esoph. (Cardiac)		1					
	Other (Specify) vet	P	P	Р '		P '	P	
	cardiac		·	 				
Peripheral vascular	Peripheral vascular	-		 	•		 	
	Other (Specify)	<u> </u>					<u> </u>	

N = new indication; P-previously cleared by FDA 510(k) 101091, E=Added under Appendix E

Prescription Use	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C
•		•

Prescription Use(Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use(21 CFR 801 Subpart C	
(PLEASE DO NOT WRITE BELOW THIS	S LINE-CONTINU	TE ON ANOTHER PAGE IF NEEDED)	
Concurrence of CDRH, Offi Division Sign-Offi Office of In Vitro Diagnostic Devices Evaluation and Safety 510(K)	fice of In Vitro Dia	gnostic Devices (OIVD)	,
510(K) Number (if known):			

¹ Includes B-Mode and Harmonic (contrast) imaging (HI)

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

³ Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)
⁴ Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

Device Name: Phase (Sector) Array Transducer P4-1c

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode	of Operati	on Trans	<u> </u>	- 15 - 25 MARTIN	د دو و در ا د ادا ها ادا دا د	magari e dan
General	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ³ ,
Ophthalmic	Ophthalmic							
	Fetal	P	Р	p		P	P	P'
	Abdominal ⁶	P	Р	P		P	P	P.
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)	l	<u> </u>				<u> </u>	
	Laparoscopic	Ţ						
	Pediatric	P	P	P		P	P	P ³
	Small Organ (Thyroid, Breast, Testes, etc.)				•			!
	Neonatal Cephalic	P	Р	P		P	P	P
General	Adult Cephalic/ trans cranial	Р	Р	P		Р	P	P ⁵
application	Trans-rectal							
•	Trans-vaginal							
	Trans-urethral							<u> </u>
•	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)		<u> </u>					
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)				;·			
	Cardiac Adult	P ¹	P	P		P	Р	P ²
	Cardiac Pediatric	P	P	P		P	Р	P ⁵
Cardiac	Trans-esoph. (Cardiac)							
	Other (Specify) (3D/4D)contrast	Р	P	Р		.P	P	P ⁵
	Peripheral Vascular	Р	Р	P		P	P	P ⁵
Peripheral vascular	Other (Specify)						ai E	

N = new indication; P=previously cleared by the FDA 510(k) K101091, E=Added under Appendix E

Prescription Use	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C

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Evaluation and Safety

510(K) Number (if known):_____

¹ Includes B-Mode and Harmonic (contrast) imaging (HI)

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

³ Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

⁴ Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic .

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[§] Freehand tissue elasticity

System Name: ZONARE ZS3 Ultrasound Diagnostic System Device Name: Phased (Sector) Array Transducer P10-4

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	ئېغى سار بىد د سرمىسا ۋايا ئاۋر بېسې د ر	Mode	of Operati	on the second			۱ - الدواود حقة محسناتات	
General	Specific (Track I & III)	B	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ⁵ .
Ophthalmic	Ophthalmic					L		<u> </u>
,	Fetal	P	P _	P		P	Р	P:
	Abdominal ⁶	P	P	P		P	P	Þ,
	Intra-operative (Specify) ⁷	P	Р	P		P	P	P ⁵
	Intra-operative (Neuro)	Р	Р	P		Р	Р	P ⁵
	Laparoscopic							
	Pediatric	Р	Р	P		Р	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)			, .		,		
	Neonatal Cephalic	P	Р	P		P	P	P ³
General	Adult Cephalic/ trans cranial	Р	Р	P	·	P	P	P ⁵
application	Trans-rectal		Ī					
	Trans-vaginal							
	Trans-urethral							·
	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal						ļ	,
	Other (Specify)							_
	Cardiac Adult	P	P	P		Р	P	P ³
	Cardiac Pediatric	P	P	P		P	P	P ⁵
Cardiac	Trans-esoph (Cardiac)							<u> </u>
	Other (Specify) (3D/4D)							
	Peripheral Vascular	P	P	P		Р	P	P ³
Peripheral vascular	Other (Specify)							

N = new indication; P=previously cleared by the FDA 510(k) K101091, E=Added under Appendix E

Includes B-Mode and Harmonic (contrast) imaging (HI) Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF) Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD) Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD) Color M-Mode (CM) Abdominal includes renal, GYN/Pelvic Intra operative include abdominal, thoracic (cardiac) and vascular (PV) Freehand tissue elasticity	
Prescription Use AND/OR Over-The-Counter Use	
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C	-
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Division Sign-Off Office of In Vitro Diagnostic Devices Evaluation and Safety 510(K) 170703	age 1 of
510(K) Number (if known):	

Device Name: Endo-Cavity Transducer E9-4

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode	of Operati	on: ' '	- 1 .54	1 S	and the second s	41. E - 2.
General (Track I Only)	Specific (Track I & HI)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴ ,	Other ^{5, 8}
Ophthalmic	Ophthalmic	<u> </u>					ļ	
	Fetal	Р	P	P		P	P	P ⁵ .
	Abdominal		1.				<u> </u>	
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	1						
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic			1.				
General	Trans-rectal	Р	P	P		P	P	P ⁵
application	Trans-vaginal	P	P	P		P	Р	P ³
аррисации	Trans-urethral							
	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)							-
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify) (3D/4D)				,			
	Cardiac Adult							
Cardina	Cardiac Pediatric		1					
Cardiac	Trans-esoph. (Cardiac)		Ī					
	Other (Specify)		1	· 1				
7.1	Peripheral vascular							
Peripheral vascular	Other (Specify)							

N = new indication:	P=previously cleared	d by FDA 510(k) K101091.	. E=Added under Appendix E

Prescription Use	AND/OR	Over-The-Counter Use	
(Part 21 CFR 801 Subpart D)	•	(21 CFR 801 Subpart C	

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Division Sign-Off			•	
Office of In Vitro Diagnostic Devices	S			
Evaluation and Safety		•		

¹ Includes B-Mode and Harmonic (contrast) imaging (HI)

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

³ Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

⁴ Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

510(K) Num	ber (if known):	-		·						
System Name	: ZONARE ZS3 U	Iltraso	ound I) jagnost	ic Syste	m		•		•
	Endo-Cavity Tra)-4 (3D)}			
	r Use: Diagnostic ultr							follows:		
	r oder Diagnoone am			5 01 11414	no vi unui,			10110 1101		
Clinical Application	reference as a	Mode	of Operat	ion			S. 190 A 18		7	
General	Specific	В	М	PWD ²	CWD	Color	Combined	Other ^{5, 8}	1	
(Track I Only)	(Track I & III)	Ь	[VI	·	CWD	Doppler ³	Modes ⁴	Other		
Ophthalmic	Ophthalmic			1			<u> </u>		4	
	Fetal	P	P	P		P	P	P ⁵	4 .	
	Abdominal	_		ļ				<u> </u>	4	
•	Intra-operative (Specify) ⁷	ļ							1	
	Intra-operative (Neuro)	<u> </u>					ļ	ļ	4	
	Laparoscopic	ļ		 			ļ <u> </u>		4	
	Pediatric	,		ļ				ļ	4	
<u>n</u>	Small Organ (Thyroid,	}	1							
	Breast, Testes, etc.)	 		+				1	4	
	Neonatal Cephalic	 		+			-	 	1	
	Adult Cephalic Trans-rectal	P	P	P	<u> </u>	P	P	P3	╣.	
General	Trans-vaginal	 ' P	P	P		P	P	P ³	1	•
application	Trans-urethral	+'	+	+ -		 	- 	+	1	•
	Trans-esoph. (non-							·	1	
	Musculo-skel.				 			 	1	
	(Conventional)			<u> </u>					4	
	Musculo-skel.	!								
	(Superficial)	<u> </u>		<u> </u>				<u> </u>	-	
٠	Intra-luminal	 -	1	, · ·		· · · · · · · · · · · · · · · · · · ·		-	-	
·	Other (Specify) (3D/4D)	Р	Р	P		P	P	P ⁵		
	Cardiac Adult				· · · · · · · · · · · · · · · · · · ·	i i			1	
C 1	Cardiac Pediatric		1	1	_					
Cardiac	Trans-esoph. (Cardiac)]	
	Other (Specify)	,] .	
D 11 1 1	Peripheral vascular								_	
Peripheral vascular	Other (Specify)]	
¹ Includes B-Mode ² Includes PWD-M ³ Includes Color D	n; P=previously cleared be and Harmonic (contrast dode imaging and High Poppler (CD). Directional HHCM, B+CI CM)) imagin ulse Re Power	ig (HI) petition I Doppler	Rate PWD- (DPD), and	Mode (HPI I Power Do	RF) ppler (PD)				
⁶ Abdominal inclu	des renal, GYN/Pelvic clude abdominal, thoraci	c (cardi	ac) and v	ascular (P\	V).	-				
	Prescription Use			A	AND/OR	Ove	r-The-Count	ter Use _		

Prescription Use	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)	•	(21 CFR 801 Subpart C

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Office of In Vitro Diagnostic Devices

Evaluation and Safety 510(K) K120703

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510(K) Number (if known):	<u> </u>
System Name: ZONARE ZS3 Ulti	rasound Diagnostic System

Device Name: Linear Transducer L10-5

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode	of Operati	on -			and the second	
General	Specific	В	М	PWD ²	CWD	Color Doppler	Combined Modes ⁴	Other ^{5, 8}
(Track I Only)	(Track I & III)	<u> </u>		ļ		P	P	
Ophthalmic	Ophthalmic	Р	 	P	-	P	P	P ⁵
	Fetal	P	P	P		P	P	P ^S
	Abdominal ⁶	P	P	Р		P	P	
	Intra-operative (Specify) ⁷	P	P	Р		P	P	P.5
	Intra-operative (Neuro)	P		Р		Р	P	P ³
	Laparoscopic		_				<u> </u>	<u> </u>
	Pediatric	P	P	P .		Р	Р	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		Р	P	P ^s
	Neonatal Cephalic	P	P	P		P	P	P ₃
a 1	Adult Cephalic							
General	Trans-rectal							<u> </u>
application	Trans-vaginal		1				<u> </u>	<u> </u>
•	Trans-urethral		T				<u> </u>	·
Ē	Trans-esoph. (non-		T				1	
	Card.)			<u> </u>		ļ	1	<u> </u>
	Musculo-skel. (Conventional)	P	P	P	•	Р	P	P ^{5, 8}
•	Musculo-skel. (Superficial)	Р	Р	Р		P	Р	P ^{5, 8}
	Intra-luminal				[<u></u>			<u> </u>
·	Other (Specify)8	·		•			. ,	
	(3D/4D)	-	┩		<u> </u>		 	 `
	Cardiac Adult	 	 	 		<u> </u>	+	
Cardiac	Cardiac Pediatric	├	+	 		 -	 	
	Trans-esoph. (Cardiac)	1	+ -	+		 	1	
	Other (Specify)	-	+	+	 	 		P ³
Peripheral	Peripheral Vascular	P	P	Р		P	P	P 8
Vascular	Other (Specify) 3D/4D			14101001		<u>.</u>	E	<u> </u>

N = new indication; P=previously cleared by the FDA 510(k) K101091, E=Added under Appendix E

Prescription Use	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

itra Diagnostic Devices

Includes B-Mode and Harmonic (contrast) imaging (HI)

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

³ Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

⁴ Includes B÷M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[§] Freehand tissue elasticity

510(K) Number (if known):_	· · · · · · · · · · · · · · · · · · ·
System Name: ZONARE ZS3	Ultrasound Diagnostic System

Device Name: Linear Transducer L8-3

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	でははないのはないという。	Mode o	f Operati	on Ellin	eritiga serai	ANY CONTRACT	LIPPLET / TETT	i primara
General (Track I Only)	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ^{5,8}
Ophthalmic	Ophthalmic		ļ					
•	Fetal	P	Р	P		P	P	P ³
•	Abdominal ⁶	P	Р	P		P	P	P ⁵
	Intra-operative (Specify) ⁷	P	P	P		P	P	P ⁵
•	Intra-operative (Neuro)	P		P		Р	P	P ⁵
	Laparoscopic			L				
•	Pediatric	P	Р	P		P	P	P ⁵
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		Р	Р	P ^s
	Neonatal Cephalic	P	P	P		Р	P	P ⁵
General	Adult Cephalic							
application	Trans-rectal							
аррисации	Trans-vaginal			<u> </u>				
*	Trans-urethral							
	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)	P	Р	P		P	Р	P ^{5, 8}
	Musculo-skel. (Superficial)	P	Р	P		Р	Р	P ^{5, 8}
•	Intra-luminal							
	Other (Specify) ⁸ 3D/4D							
	Cardiac Adult							
Cardia	Cardiac Pediatric							
Cardiac	Trans-esoph. (Cardiac)					-		
	Other (Specify)							
Peripheral	Peripheral Vascular	P	Р	Р		P	Р	P ⁵
Vascular	Other (Specify) 3D/4D					1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -		

N = new indication; P=previously cleared by the FDA 510(k) K082326 & K101091, E=Added under Appendix E

Examples may include A-mode, Amplitude Doppler, 3-D imaging, Harmonic imaging, Tissue Motion Doppler, Color velocity imaging

Prescription Use	AND/OR	Over-The-Counter Use
(Part 21 CFR-801 Subpart D)		(21 CFR 801 Subpart C

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Evaluation and Safety
510(K) K120703

Includes B-Mode and Harmonic (contrast) imaging (HI)

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

³ Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

⁴ Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

^{&#}x27; Freehand tissue elasticity

510(K) Number (if known):

System Name: ZONARE ZS3 Ultrasound Diagnostic System

Device Name: Linear Transducer L12-4v

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	the solution of the solution o	Modé o	of Operati	on`			4 P	
General (Track I Only)	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ^{5,8}
Ophthalmic	Ophthalmic		Ī			I		
	Fetal			,				
	Abdominal					•		
	Intra-operative (Specify) ⁷	·						
	Intra-operative (Neuro)					ļ	•	
	Laparoscopic						l ·	
	Pediatric	P	P	P		P	Р	
	Small Organ (Thyroid, Breast, Testes, etc.)	P	Р	P	_	Р	P	
-	Neonatal Cephalic					1	,	
	Adult Cephalic		1					
General	Trans-rectal			,	_			
application	Trans-vaginal		L.					
	Trans-urethral							
,	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)	Р	P	P		Р	P	P.
	Musculo-skel. (Superficial)	P	Р	P		Р	P	Р
	Intra-luminal							
	Other (Specify) (3D/4D) (vet use too)	Р	Р	Р	•	P	P	P
	Cardiac Adult					1	1	
	Cardiac Pediatric						İ	
Cardiac	Trans-esoph. (Cardiac)							
	Other (Specify)							
	Peripheral vascular	Р	Р	P		P	Р	P
Peripheral vascular	Other (Specify)				······································	J		

N =	new indica	tion: P=previo	usly cleared by	/ FDA 510(k) K	101091, E=Added	l under appendix E.

Prescription Use	AND/OR	Over-The-Counter Use	
(Part 21 CFR 801 Subpart D)	•	(21 CFR 801 Subpart C	

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Devices

Evaluation and Safety

510(K) K120703

¹ Includes B-Mode and Harmonic (contrast) imaging (HI)

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

³ Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

⁴ Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

⁸ Freehand tissue elasticity

510(K) Number (if known):	•
System Name: ZONARE ZS3 Ultrasound Diagnosti	c Syste

Device Name: Linear Transducer L14-5sp

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	(47 美),李松,安广公之第十四 翻点	Mode	of Operati	ón 🗁 🧎 🕴	\$45 July 12	State & Comme	1. 4. 1. 15 E.	A Page A
General (Track I Only)	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ¹	Combined Modes ⁴	Other ^{5, 8}
Ophthalmic	Ophthalmic							
Opiniannic	Fetal	Р	P	P		P	P	P ⁵
	Abdominal ⁶	P	P	P		Ρ .	Р	P ³
	Intra-operative (Specify) ⁷	Р	P	Р		P	P	P ⁵
	Intra-operative (Neuro)	P		P		P	P	P ⁵
	Laparoscopic							
	Pediatric	P	Р	P		P.	P	P ⁵
٠.	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	Р .		P	P	P ³ P ⁸
	Neonatal Cephalic	P	P	P		P	P	P ⁵
General	Adult Cephalic							
application	Trans-rectal						· · ·	
application	Trans-vaginal	-						
	Trans-urethral							
•	Trans-esoph. (non- Card.)				٠			
	Musculo-skel. (Conventional)	P	P ·	P		P	P	P ^{5, 8}
	Musculo-skel. (Superficial)	P	P	Р.		Р	Р	P ^{5, 8}
	Intra-luminal							
	Other (Specify) ⁸ 3D/4D							
	Cardiac Adult		1		•			
Cardiac	Cardiac Pediatric							
Cardiac .	Trans-esoph. (Cardiac)							
_	Other (Specify)							<u> </u>
Peripheral	Peripheral Vascular	P	Р	P		Р	P	P ⁵
Vascular	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by the FDA 510(k) K082326 & K101091, E=Added under Appendix E

Examples may include A-mode, Amplitude Doppler, 3-D imaging, Harmonic imaging, Tissue Motion Doppler, Color velocity imaging

Prescription Use	AND/OR	Over-The-Counter Use	
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C	

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Office of In Vitro Diagnostic Devices

Evaluation and Safety K17070

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¹ Includes B-Mode and Harmonic (contrast) imaging (HI)

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

³ Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[§] Freehand tissue elasticity

510(K) Number (if known):_	
System Name ZONARE ZS3	Ultrasound Diagnostic System

Device Name: Linear Transducer L14-5w

Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	And the late of the second	Mode o	of Operati	on' 🏥 🕆		25. (2 w (5 Y))	The state of the s	(j. 132 . iv.
General	Specific	В	М	PWD ²	CWD	Color	Combined	Other ^{5, 8}
(Track I Only)	(Track I & III)		· · · ·	<u> </u>		Doppler ³	Modes⁴	
Ophthalmic	Ophthalmic			<u> </u>			<u> </u>	
	Fetal	P	P	P		P	P	P ⁵
	Abdominal ^b	P	P	P		P	P	P ⁵
	Intra-operative (Specify) ⁷	P	Р	Р .		P	P	P ⁵
	Intra-operative (Neuro)	Р	_	P		P	P	P ⁵
	Laparoscopic							
•	Pediatric	P	Р	P		P	P	P ²
	Small Organ (Thyroid, Breast, Testes, etc.)	P	Р	Р		P	P	P ⁵ P ⁸
	Neonatal Cephalic	P	Р	P		P	P	P ⁵
C 1	Adult Cephalic					ĺ		
General application	Trans-rectal					•		
application	Trans-vaginal			1				
	Trans-urethral				,		, ,	
	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)	P	P	Р		Р	Р	P ^{5, 8}
	Musculo-skel. (Superficial)	Р	Р	P		P	P	P ^{5.8}
	Intra-luminal							
	Other (Specify) ⁸ 3D/4D							
	Cardiac Adult						·	
C 41	Cardiac Pediatric							
Cardiac	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral	Peripheral Vascular	Р	Р	Р		P	Р	P ⁵ P ⁸
Vascular	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by the FDA 510(k) K101091, E=Added under Appendix E

Examples may include A-mode, Amplitude Doppler, 3-D imaging, Harmonic imaging, Tissue Motion Doppler, Color velocity imaging

Prescription Use	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Devices

Evaluation and Safety

Page 1 of

¹ Includes B-Mode and Harmonic (contrast) imaging (HI)

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

³ Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

⁴ Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

⁵ Color M-Mode (CM)

⁶ Abdominal includes renal, GYN/Pelvic

⁷ Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[§] Freehand tissue elasticity

General (Track I Only)	Specific (Track I & III)	В	1 .	1				
Ophthalmic		1 5	M	PWD ²	CWD	Color Doppler ³	Combined Modes [‡]	Other ^{5, 3}
Obnilaimic	Ophthalmic		1				11111111	
	Fetal	1						†
	Abdominal		1					
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)			· ·		1		1
	Laparoscopic	1		T ·				ì
	Pediatric							T .
Bre	Small Organ (Thyroid,	Τ						
	Breast, Testes, etc.)	<u> </u>						<u> </u>
	Neonatal Cephalic	L				1		
	Adult Cephalic							
applications	Trans-rectal						ļ	1
	Trans-vaginal	ļ		ļ			<u> </u>	ļ
	Trans-urethral	ļ		ļ				ļ
	Trans-esoph (non- Card.)	P	P	Р	*	.Р	P	P ⁵
	Musculo-skel. (Conventional)							
	Musculo-skel.	†		1			·	
	(Superficial)	}	1]	
	Intra-luminal	1		<u> </u>		İ		
	Other (Specify) (3D/4D)							
	Cardiac Adult		1	1				
C4:	Cardiac Pediatric		Ì					
Cardiac Peripheral Vessel N = new indication	Trans-esoph. (Cardiac)	P	P	P		P	P	P ⁵
•	Other (Specify)							
Cardiac Peripheral Vessel N = new indication Includes B-Mode	Peripheral Vessel					<u> </u>		
rempheral vessel	Other (Specify)							

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Division Sign-Off Office of In Vitro Diagnostic Devices Evaluation and Safety

510(K) K120703

System Name: Device Name:	er (if known):	x PLUS	ICE C	atheter r	nodel # VI	F-PM Part #			elf) (P9-3ic)
Clinical Application	and the same	Mode o	f Operation	on .				7	
General	Specific	R	М.	PWD ²	CWD	Color	Combined	Other ^{5, 8}	

Clinical Application	and the same of	Mode	of Operati	on, .	. ;		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
General (Track I Only)	Specific (Track I & III)	В	М	PWD ²	CWD	Color Doppler ³	Combined Modes ⁴	Other ^{5, 8}
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal							
	Intra-operative (Specify) ⁷							
	Intra-operative (Neuro)							
	Laparoscopic			1				
•	Pediatric			1				
	Small Organ (Thyroid, Breast, Testes, etc.)							
•	Neonatal Cephalic							
	Adult Cephalic							
General .	Trans-rectal	Ĭ						
application	Trans-vaginal		l					
применен	Trans-urethral					,		
	Trans-esoph. (non- Card.)							
	Musculo-skel. (Conventional)							
•	Musculo-skel. (Superficial)							
	Intra-luminal	;	1					
• •	Other (Specify) (3D/4D)							· .
	Cardiac Adult							
c .:	Cardiac Pediatric							
Cardiac	Trans-esoph. (Cardiac)			·				
•	Other (Intra-Cardiac)	P	Р.	P		P		
D : 1 1	Peripheral vascular							
Peripheral vascular	Other (Specify)							

N = new indication; P=previously cleared by FD	A 510(k) K101091	, ST Jude K 031066	K073709	E=Added under	Appendix E
¹ Includes B-Mode and Harmonic (contrast) ima					

Prescription Use(Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C	4 - **
•			

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Office of In Vitro Diagnostic Devices

Evaluation and Safety

² Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)
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⁴ Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

Color M-Mode (CM)

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[§] Freehand tissue elasticity